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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,818	06/18/2001	James F. McGuckin JR.	1243	2564
<del>,</del>	590 04/24/2003			
Neil D. Gersh	ion		EXAMI	NER
Chief Patent Counsel Rex Medical		-	PHANIJPHAND, GWEN G	
2023 Summer St., Suite 2 Stamford, CT 06905			ART UNIT	PAPER NUMBER
<b>,</b>			3731 DATE MAILED: 04/24/2003	8

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
•		09/883,818	MCGUCKIN ET AL.
Office Action Summary		Examiner	Art Unit
		Gwen Phanijphand	3731
	The MAILING DATE of this communication app		
THE I - Exter after - If the - If NO - Failur - Any r	ORTENED STATUTORY PERIOD FOR REPLIMAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing dispatent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be to y within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONI	mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).
1)🖂	Responsive to communication(s) filed on 03 /	February 2003 .	
2a)⊠	This action is <b>FINAL</b> . 2b) Th	nis action is non-final.	
3) 🗌 Dispositi	Since this application is in condition for allowed closed in accordance with the practice under on of Claims		
4)⊠	Claim(s) 1-13 and 19-27 is/are pending in the	application.	
	4a) Of the above claim(s) <u>14-18</u> is/are withdraw	wn from consideration.	
5)	Claim(s) is/are allowed.		
6)⊠	Claim(s) 1-13 and 19-27 is/are rejected.		
7)	Claim(s) is/are objected to.		
•	Claim(s) are subject to restriction and/o on Papers	or election requirement.	
9) 🔲 -	The specification is objected to by the Examine	er.	
10)🛛 -	The drawing(s) filed on <u>18 June 2001</u> is/are: a)	□ accepted or b) □ objected to by	the Examiner.
	Applicant may not request that any objection to th	e drawing(s) be held in abeyance.	See 37 CFR 1.85(a).
11) 🔲 -	The proposed drawing correction filed on	_ is: a)□ approved b)□ disappr	oved by the Examiner.
	If approved, corrected drawings are required in re	ply to this Office action.	
12) 🔲 🗆	Γhe oath or declaration is objected to by the Ex	aminer.	
Priority u	nder 35 U.S.C. §§ 119 and 120		
13)[	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(	a)-(d) or (f).
a)[	☐ All b) ☐ Some * c) ☐ None of:		
	1. Certified copies of the priority document	s have been received.	
	2. Certified copies of the priority document	s have been received in Applicat	tion No
	3. Copies of the certified copies of the prio application from the International Buse the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).	_
	.cknowledgment is made of a claim for domesti	·	
<b>a</b> )	The translation of the foreign language pro	ovisional application has been re	ceived.
Attachment	_		
1) Notice 2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u>	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)
I.S. Patent and Tr PTO-326 (Re		ction Summary	Part of Paper No. 2

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# RESPONSE TO AMENDMENT

Claim Rejections - 35 U.S.C. 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-3, 7-11, 13, 20, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,733,294 to Forber et al.

Regarding claim 1, Forber et al. disclose in Fig. 1 a device that is capable of being a filter comprising a first filtering portion (the left portion of 22 closer to the center), a first anchoring portion (the left portion of 22 closer to the end), and a transverse dimension of the first filtering portion in an expanded configuration being less than the transverse dimension of the first anchoring portion in an expanded configuration. Forber et al. disclose an end portion of the first anchoring portion spaced from the first filtering portion and converging to a first converging section (27). Forber et al. disclose a second filtering portion (the right portion of 22 closer to the center), a second anchoring portion (the right portion of 22 closer to the end), and a transverse dimension of the second filtering portion being less than a transverse dimension of the second anchoring portion. An end portion of the second anchoring portion is spaced from the first filtering portion and converges to a second converging section (23). The first and second filtering portions are positioned closer to each other than the first and second anchoring portions. The anchoring portions are formed on first and second opposite portions of the device.

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Regarding claim 2, Forber et al. disclose in Fig. 1 a sleeve (25) positioned between the first and second filtering portions.

Regarding claim 3, Forber et al. disclose in Fig. 1 the filtering and anchoring portions formed by three wires (22).

Regarding claim 7, Forber et al. disclose in Fig. 1 the transverse dimensions of the first and second anchoring portions (22) and filtering portions (22) being substantially equal.

Regarding claim 8, Forber et al. disclose in Fig. 1 the filtering portions progressively increasing in diameter towards its respective anchoring portion.

Regarding claim 9, Forber et al. disclose in Fig. 1 a device capable of being a filter having a first portion (left 22), a second portion (right 22), and an intermediate portion between the first and second portions. The first portion increases in diameter from the intermediate portion towards a first end and the second portion increases in diameter from the intermediate portion towards a second end. As shown in Fig. 4, a region closer to the intermediate portion is capable of being a filter portion and a region further from the intermediate portion can be used as an anchoring portion, wherein elements of the portions (22) extend radially distally in a first direction and bend back (at 50) to extend proximally in a second direction. The elements of the portions radiate from a common center outwardly, and hence are considered to radiate distally.

Regarding claim 10, Forber et al. disclose in Fig. 1 a device capable of being a filter formed by at least one wire (22), each wire forming a part of the first (left and right portions closer to the center), second (left and right portions closer to the ends, 50), and intermediate portions (portions retained within 25).

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Regarding claim 11, Forber et al disclose in Fig. 1 a retaining sleeve at the intermediate portion (25) to retain the at least one wire.

Regarding claim 13, Forber et al. disclose the device being composed of shape memory metal (col. 3, II. 24-26)

Regarding claim 20, Forber et al. disclose in Fig. 1 the first and second filtering portions (22) converging and being retained by a sleeve (25).

Regarding claim 21, Forber et al. disclose in Fig. 1 the filter comprising a retaining sleeve at the first converging section (27) and a retaining sleeve at the second converging section (23).

Regarding claim 23, Forber et al. disclose in Fig. 1 the anchoring portion converging at a first end to form a first converging section (27) and at a second end to form a second converging section (23).

Regarding claim 24, Forber et al. disclose the apparatus comprising a retention member (27) at the first converging section and a retention member (23) at the second converging section.

Regarding claim 25, Forber et al. further comprise a retention member (25) for retaining a converging region of the filter portion.

2. Claims 1, 2, 4, 7, 8, 20, 21, 22, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,746,767 to Smith.

Regarding claim 1, Smith discloses in Fig. 2 a filter comprising a first filtering portion (left portion 16, the part of 16 closer to the center), a first anchoring portion (left portion of 16, the part of 16 closest to the right end), and a transverse dimension of the first filtering portion in an expanded configuration being less than the transverse dimension of the first anchoring portion in an expanded configuration. An end portion of the first anchoring portion is spaced from the

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first filtering portion and converges to a first converging section. The end portion of the first anchoring portion (leftmost 16) converges at elements 18 (which comprises 19 and 21) or 20 (col. 2, II. 53-58). Smith discloses in Fig. 2 a second filtering portion (right portion of 16, closer to the center), a second anchoring portion (right portion of 16 closer to the right end), and a transverse dimension of the second filtering portion being less than a transverse dimension of the second anchoring portion. An end portion of the second anchoring portion is spaced from the first filtering portion and converges to a second converging section. The end portion of the second anchoring portion (rightmost 16) converges at elements 18 (which comprises elements 19 and 21) or 20 (col. 2, II. 53-58). The first and second filtering portions are positioned closer to each other than the first and second anchoring portions, and the anchoring portions are formed on first and second opposite portions of the filter.

Regarding claim 2, Smith discloses in Fig. 1 a sleeve (26) positioned between the first and second filtering portions (left and right 16). The filtering portions converge inside the hubs, 22 and 24 (Fig. 2), and in Fig. 2, the hubs (22, 24) combine to form the sleeve, 26, which can be positioned between the first and second filtering portions (col. 2, II. 58-60).

Regarding claim 4, Smith discloses in Fig. 2 a first anchoring member, left element 19 of element 18, extending from the first anchoring portion and a second anchoring member, right element 19 of element 18, extending from a second anchoring portion (col. 2, II. 54-56).

Regarding claim 7, Smith discloses in Fig. 2 the transverse dimensions of the first and second anchoring portions (part of 16 closer to the ends) and filtering portions (part of 16 closer to the center) being substantially equal.

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Regarding claim 8, Smith discloses in Fig. 2 the filtering portions (part of 16 closer to the center) progressively increasing in diameter towards its respective anchoring portion (part of 16 closer to the ends).

Regarding claim 20, Smith discloses in Fig. 1 the first and second filtering portions converging and being retained by a sleeve (26). The filtering portions converge inside the hubs, 22 and 24 (Fig. 2), as the hubs combine to form sleeve 26 (col. 2, 1l. 56-60).

Regarding claim 21, Smith disclose in Fig. 2 the filter comprising a retaining sleeve at the first converging section (24) and a retaining sleeve at the second converging section (22). The portions also converge at element 18, which comprises elements 19 and 21. Element 18 can also serve as a sleeve for the converging sections of elements 16.

Regarding claim 22, Smith discloses in Fig. 2 the anchoring members (19) having opposing sharpened ends (col. 2, Il. 54-55).

Regarding claim 26, Smith discloses in Fig. 2 a filter having a first portion (left 16), a second portion (right 16), and an intermediate portion between the first and second portions. The first portion increases in diameter from the intermediate portion towards a first end, and the second portion increases in diameter from the intermediate portion towards a second end. A region closer to the intermediate portion forms a filter portion (portions of 16 closer to the center), and an anchoring portion (portions of 16 closer to the left and right ends) is formed at the first end and second end. An end region of each anchoring region converges to form a converging section (elements 18 and 20; col. 2, II. 53-58) spaced from the filter portion.

Regarding claim 27, Smith further comprises in Fig. 2 a connecting element (19, 21, 22, 24) at each converging section.

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### Claim Rejections - 35 U.S.C. 102(e)

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 9-13 and 19 are rejected under 102(e) as being anticipated by U.S. Patent No. 6,251,122 B1 to Tsukernik.

Regarding claim 9, Tsukernik discloses in Fig. 3 a filter having a first portion (32, the length between 72 and 76), a second portion (42, the length between 74 and 78), and an intermediate portion (50) between the first and second portions. The first portion increases in diameter from the intermediate portion towards a first end (36, 76) and the second portion increases in diameter from the intermediate portion towards a second end (46, 78). A region closer to the intermediate portion forms a filter portion and a region further from the intermediate portion forms an anchoring portion (60, 62, 76, 78), wherein elements of the portions (72, 74) extend radially distally in a first direction and bend back (at 76 and 78) to extend proximally in a second direction. The ends, 76 and 78, extend in a first direction and then bend back toward the center in a second direction. The elements of the portions also radiate from a common center outwardly, and hence are considered to radiate distally.

Regarding claim 10, Tsukernik discloses in Fig. 3 a filter formed by at least one wire (32, 42, lengths between 74 and 78 and 72 and 76), each wire forming a part of the first, second, and intermediate portions.

Regarding claim 11, Tsukernik discloses a retaining sleeve at the intermediate portion (72, 74) to retain the at least one wire.

Regarding claim 12, Tsukernick disclose in Fig. 3 a member (60, 62) to engage the vessel wall.

Regarding claim 13, Tsukernik discloses the filter being composed of shape memory metal (col. 5, II. 23-24)

Regarding claim 19, Tsukernik discloses in Fig. 3 the filter further comprising a plurality of anchoring members (60, 62, 76, 78) spaced from a proximalmost and distalmost end of the filter.

#### Claim Rejections - 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,746,767 to Smith.

Regarding claims 3, 5, and 6, Smith discloses in Fig. 2 first and second filtering and anchoring portions, each having a lumen to receive the wires, each having first and second

opposing sharpened ends for engaging the vessel wall, and a collapsed filter with wires in an elongated configuration substantially parallel to a longitudinal axis of the filter (col. 3, II. 11-17), but Smith does not disclose the portions formed by three wires. In col. 4, II.34-39, Smith does disclose that fewer struts may be used. The number of wires or struts affects the size and number of emboli captured by the filter, and thus, it would have been an obvious to one having ordinary skill in the art at the time of the invention was made to disclose that the filter could be composed of three struts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

### Response to Arguments

Applicant's arguments with respect to claims 1-13 and 19-27 have been considered but are most in view of the new grounds of rejection.

Regarding the claim 1, Smith discloses in Fig. 2 the elements, 16, converging together at elements 18. The elements, 16, further converge at 20. In col. 2, Il. 56-58, "the joining ends 20 of struts 16 of first unit 12 are joined at a hub 22 and the joining ends 20 of the respective struts 16 of second unit 14 are joined at hub 24."

Regarding claim 9, Tsukernik discloses an element of the anchoring portions extending radially distally and bending back in a different direction. The definition of radially is "radiating from or converging to a common center (www.dictionary.com)." The elements, 32, 42, and the lengths between 74 and 78 and 72 and 76 all extend from the center and extend distally. The lengths between 74 and 78 and 72 and 76 bend back in a different direction a 76 and 78.

#### Conclusion

The Prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,447,531 B1 to Amplatz

U.S. Patent No. 6,123,715 to Amplatz

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP

April 17, 2003

Gwen Phanijphand Patent Examiner Art Unit 3731

Michael J. Milano

Supervisory Patent Examiner Technology Center 3700